Initial Approval: July 13, 2016
Revised Dates: October 12, 2016

CRITERIA FOR PRIOR AUTHORIZATION

Probuphine® (buprenorphine implant for subdermal administration)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Buprenorphine implant for subdermal administration (Probuphine®)

CRITERIA FOR INITIAL PRIOR AUTHORIZATION FOR BUPRENORPHINE IMPLANT FOR SUBDERMAL ADMINISTRATION (must meet all of the following):

- Patient must have a diagnosis of opioid dependence
- Patient must be actively involved in addiction treatment
- Prescriber must have a current XDEA number
- Prescriber must practice in Kansas or a border city and be an enrolled provider with plan
- Patient must currently be clinically stabilized on 8mg per day or less of buprenorphine or buprenorphine/naloxone (treatment equal to or greater than 90 days, without any need for supplemental dosing adjustments)
- Patient must have had adherence issue to oral Buprenorphine or Buprenorphine/Naloxone therapy
- Must be inserted and removed by a trained Healthcare Provider who has successfully completed a live training program on insertion and removal procedures and become certified with the Probuphine REMS program

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION FOR BUPRENORPHINE IMPLANT FOR SUBDERMAL ADMINISTRATION: (Must meet all initial criteria and the following)

- Patient has not received any other narcotic agents since last prior authorization approval
- Prescriber has reviewed the patient's K-TRACS profile and confirmed the patient is not receiving any narcotic agents in addition to their buprenorphine agent (information regarding the K-TRACS program may be found on The Kansas Board of Pharmacy web site)
- If patient has received opioids the prescriber must validate the reason for use and include information regarding the patient treatment plan
- Patient has not required the use of supplemental transmucosal dosing

LENGTH OF APPROVAL: 6 months for a total of 4 implants

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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DATE	DATE

Notes:

- Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.
- Four Probuphine implants are inserted subdermally in the upper arm for 6 months of treatment and are removed by the end of the sixth month.
- Consider the following factors in determining clinical stability and suitability for Probuphine treatment: period free from illicit opioid drug use; stability of living environment; participation in a structured activity/job; consistency in participation in recommended behavioral therapy/peer support program; consistency in compliance with clinic visit requirements; minimal to no desire or need to use illicit opioids; period without episodes of hospitalizations (addiction or mental health issues), emergency room visits or crisis interventions; social support system.
- Although some patients may require occasional supplemental dosing with buprenorphine, patients should not be provided with prescriptions for transmucosal buprenorphine-containing products for as-needed use. Instead, patients who feel the need for supplemental dosing should be seen and evaluated promptly. Ongoing use of supplemental dosing with transmucosal buprenorphine indicates that the amount of buprenorphine delivered by PROBUPHINE is not adequate for stable maintenance. Consider use of alternate buprenorphine products for maintenance of treatment.
- Probuphine is available only through a restricted program under a REMS, because of the risk of complications of migration, protrusion and expulsion, and nerve damage associated with the insertion and removal.

Comparable Doses
Suboxone (buprenorphine/naloxone) 8/2 mg
Subutex (buprenorphine) 8 mg
Bunavail (buprenorphine/naloxone) 4.2/0.7 mg
Zubsolv (buprenorphine/naloxone) 5.7/1.4 mg